FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
October 30, 2014

AGENDA

The committee will discuss new drug application (NDA) 206316, edoxaban tablets, submitted by Daiichi Sankyo, Inc., for the prevention of stroke and systemic embolism (blood clots other than in the head) in patients with nonvalvular atrial fibrillation (A Fib; abnormally rapid and chaotic contractions of the atria, the upper chambers of the heart).

8:00 a.m.	Call to Order Introduction of Committee	**A. Michael Lincoff, MD** Chairperson, CRDAC
8:05 a.m.	Conflict of Interest Statement	**Kristina Toliver, PharmD** Acting Designated Federal Officer, CRDAC
8:10 a.m.	Opening Remarks	**Norman Stockbridge, MD, PhD** Director Division of Cardiovascular and Renal Products (DCaRP) Office of Drug Evaluation I (ODEI) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**SPONSOR PRESENTATIONS**	
	Introduction	**Mahmoud Ghazzi, MD, PhD** Executive Vice President, Global Head of Development Daiichi Sankyo, Inc.
	Clinical Landscape	**Peter Kowey, MD, FAHA, FACC, FHRS** Professor of Medicine and Clinical Pharmacology Thomas Jefferson University Head of Cardiology, Main Line Health William Wikoff Smith Chair, Lankenau Heart Institute
	Edoxaban: Clinical Development Program in AF	**Michele Mercuri, MD, PhD** Senior Vice President Clinical Development and Chief Medical Advisor Daiichi Sankyo Pharma Development Daiichi Sankyo, Inc.
	ENGAGE AF-TIMI 48 Primary Clinical Outcomes	**Robert P. Giugliano, MD** Senior Investigator TIMI Study Group Associate Physician, Cardiovascular Division Brigham & Women's Hospital Associate Professor of Medicine Harvard Medical School

AGENDA (cont.)

	SPONSOR PRESENTATIONS (CONT.)	
	Subgroup Analyses	**Glenn Gormley, MD, PhD** Senior Executive Officer and Global Head of Research Development, Daiichi Sankyo Co., Ltd Executive Chairman and President Daiichi Sankyo, Inc.
	Clinical Perspectives and Benefit:Risk	**Eugene Braunwald, MD** Founding Chairman TIMI Study Group Brigham & Women's Hospital Distinguished Hersey Professor of Medicine Harvard Medical School Chairman, ENGAGE AF-TIMI 48
9:50 a.m.	Clarifying Questions to the Presenters	
10:20 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Statistical Considerations ENGAGE AF Trial	**John Lawrence, PhD** Statistical Reviewer Division of Biometrics I Office of Biostatistics Office of Translational Science (OTS), CDER, FDA
	How to Approach the Observed Decreased Efficacy of Edoxaban in Subjects with Normal Renal Function	**Melanie Blank, MD** Medical Officer DCaRP, ODEI, OND, CDER, FDA
	Dosing Considerations Based on Renal Function	**Justin Earp, PhD** Pharmacometrics Reviewer Division of Pharmacometrics Office of Clinical Pharmacology, OTS, CDER, FDA
11:30 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Martin Rose, MD, JD** Clinical Team Leader DCaRP, ODEI, OND, CDER, FDA
2:20 p.m.	Questions to the Committee and Committee Discussion	
3:00 p.m.	**BREAK**	
3:10 p.m.	Questions to the Committee and Committee Discussion (cont.)	
5:30 p.m.	**ADJOURNMENT**	